REMARKS

Favorable reconsideration is respectfully requested in view of the preceding amendments and the following comments.

Newly presented claims 15 to 27 find complete antecedent support in the original claims which they replace, as indicated parenthetically following each claim number.

The rejection of claims 1 to 8, 11 and 14 "under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,254,884" is respectfully traversed. Claim 1 calls for a composition which consists of somatotropin, a lipid-soluble vitamin, and a pharmaceutically acceptable lubricant. All other claims are at least ultimately dependent upon and thus have all of the limitations of claim 1 (corresponding to new claim 15). The Examiner appears to equate the reference's delaying agent with Applicants' lubricant. Nothing is found in the reference or other applied art that would equate the two distinct respective components. The only delaying agent apparently referred to in the reference document is lecithin, and there is no indication that lecithin is regarded as a lubricant. Although the structure of lecithin may include components of different acids, it is not equivalent to any of those acids. The chemistry referred to in paragraph 2 of the Office Action is similar to concluding that CH_2O comprises H_2O; or that H_2O_2 comprises water. Drinking the former of each of the two comparisons would certainly not be advisable. The differences between the respectively noted acids and lecithin are readily apparent. The reference does not in any way suggest that either oleic acid, linoleic acid or linolenic acid is a suitable delaying agent for the reference's purpose. Were either of those acids actually contemplated, such would clearly have been disclosed.

The rejection of claims 8 to 13 "under 35 U.S.C. 112, second paragraph" is also respectfully traversed. With regard to claim 8 (new claim 22) the "or other material" is specifically limited in the same manner as original claim 13, and thus overcomes this ground of rejection in the same manner as claim 13. With regard to the phrase "or the like" in claims 9 to 13, that phrase does not appear in any of the newly presented claims. This ground of rejection is thus completely overcome.

The rejection of claims 1 to 4, 6 to 8, 11 and 14 "under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,520, 927" (Kim) is also respectfully traversed.

The object of the Kim patent is to provide a slow releasing bioactive composition in order to maintain biological activities of bioactive polypeptides having short half-life in vivo. Somatotropin is a very suitable example of bioactive polypeptides. On the other hand, the object of the present invention is to provide a composition comprising somatotoropin and vitamins with decreased injection frequency, increased productivity of milk, decreased incidence of mastitis, and especially improved syringeability.

In order to accomplish the above object, Kim's invention provides a composition which comprises a lyophilized mixture including somatotropin and a release delaying agent, suspending said lyophilized mixture in a tocopherol compound to form a suspension, wherein said *tocopherol compound (also known as vitamin E) is an element used for the purpose of more slowly releasing polypeptide, such as somatotropin, which is present in an amount of 1 to 10% by weight based on the total weight of the composition.* On the other hand, the present invention provides a composition which comprises somatotropin, at least one pharmaceutically acceptable lubricant and at least one lipid-soluble vitamin, which is vitamin A or its derivative, or vitamin E

or its derivative, wherein *the lipid-soluble vitamin is an element for the purpose of decreasing the incidence of mastitis. Also, the somatotropin is present in an amount of 10 to 50% by weight based on the total weight of the composition.*

Although Kim "includes choline derivatives among the delaying agents used in the invention", the choline derivatives used are significantly different from oleic acid, linoleic acid, or linolenic acid, as expressly called for by, e.g., claim 11 (new claim 25). The choline derivatives referred to are phosphatidyl choline, lysophospholipid, plasmalogen, sphingomyelin, etc. Which of those choline derivatives is regarded as a lubricant, and what basis is there in the applied prior art to confirm this? Paragraph 8 of the Office Action further states that the " choline disclosed in the prior art as delaying agent comprises oleic, linoleic and linolenic acid." (This is like asserting that carbon tetrachloride comprises carbon and chlorine.) Applicants respectfully request that the basis for this unsupportable allegation be explained on the record or expressly withdrawn. Choline is 2-hydroxy-N,N,N-trimethylethanaminium; how this "comprises oleic, linolenic and linolenic acid" is not understood. The Office Action does not present a single reference to a lubricant for compositions of the type instantly claimed.

The rejection of claims 1 to 8, 11 and14 "under 35 U.S.C. 102(e) as being anticipated by WO 99/43342" ('342) is also respectfully traversed.

The object of the '342 invention is to provide a method for increasing milk production and decreasing incidence of mastitis of dairy cattle. On the other hand, the core object of the present invention is to provide a composition comprising somatotoropin with improved syringeability, especially under low temperature.

In order to accomplish the above object, the '342 invention provides a pharmaceutical

composition which comprises somatotropin, at least two kinds of lipid-soluble vitamins which are selected from the group consisting of vitamin A, vitamin D and vitamin E, and *a delaying agent for a sustained-release effect of somatotropin.* On the other hand, the present invention provides a composition which comprises somatotropin, at least one lipid-soluble vitamin (vitamin A or its derivative, or vitamin E or its derivative) and at least one pharmaceutically acceptable *lubricant, which improves syringeability under cold temperature conditions, which has been a defect of conventional somatotropin formulations using vitamins.*

Lecithin is a mixture of the diglycerides of stearic, palmitic, and oleic acids, linked to the choline ester of phosphoric acid; it is not the same as any of oleic acid, linoleic acid and linolenic acid. Also, it does not have the same properties as any of those acids. Moreover, no applied prior art even remotely indicates that lecithin is a lubricant in the context of Applicants' claimed subject matter.

Applicants respectfully request an explanation of the right to rely upon the U.S. filing date in the absence of reliance upon a patent issued on the application filed in the United States.

As employees of LG CHEMICAL LTD., Kim and Ryoo, inventors of the subject application were also inventors of the published invention instantly relied upon. Thus, the published '342 invention was derived from the inventors of this application.

A basic misconception is in the presumption that "lecithin disclosed in the prior art as delaying agent comprises oleic, linoleic and linolenic acids. This is inaccurate. Although lecithin may comprise elements of those acids, it does not comprise those acids and is not equivalent to those acids any more than saying that ethanol comprises methanol.

The rejection of claims 1 to 14 "under 35 U.S.C. 103(a) as being unpatentable over U.S.

Patent 6,497,886" (Breitenbach) is also respectfully traversed. Breitenbach relates to 1,3-bis-(N–lactamyl) propanes and their use as solvents in pharmaceutical and cosmetic compositions (column 1, second complete paragraph). Since Applicants' sole independent claim calls for a composition "which consists of" specified components other than 1,3-bis-(N-lactamyl) propanes, nothing is found in Breitenbach that would even remotely suggest or render obvious that which is called for by each of Applicants' claims. Applicants do not find where Breitenbach discloses his essential component as a lubricant in the context of Applicants' claims. As Applicants' claims are in "consists of" terminology, it expressly excludes, as an essential component, that which is not expressly called for by claim 15 (former claim 1).

In order to accomplish Breitenbach's object, his invention provides pharmaceutical or cosmetic compositions comprising a specific solvent with excellent dissolving capacity for the active ingredient, miscibility with other solvents and physiological tolerability. On the other hand, Applicants' claimed invention provides a composition which consists of somatotropin, a pharmaceutically acceptable lubricant and a lipid-soluble vitamin, wherein somatotropin is an element for the purpose of increasing productivity of milk, and the lipid-soluble vitamin is an element for decreasing incidence of mastitis. The composition does not include the solvent which is essential to Breitenbach's disclosure.

Having overcome all outstanding grounds of rejection, the subject application is now in condition for allowance, and early action toward that end is respectfully solicited.

Respectfully submitted,
JACOBSON HOLMAN PLLC

By _____
Yoon S. Ham
Reg. No. 45,307

400 Seventh Street, N.W.
Washington, D.C. 20004-2201
(202) 638-6666
Direct: (202) 393-5350
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